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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| EXAMINER | |
|---|---|
| CHAUDHURI, ANIRUDDHO RAY | |
| **ART UNIT** | **PAPER NUMBER** |
| 1644 | |

DATE MAILED: 11/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/774,076 | LANDOLFI ET AL. | |
| | Examiner | Art Unit | |
| | Aniruddho R Chaudhuri | 1644 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

## DETAILED ACTION

### Sequence Compliance

1. The instant application is in sequence compliance for patent applications containing nucleotide sequence and/or amino acid sequence disclosures.

2. The following is noted: Claims 33, 37 include a recitation of a "method of treating psoriasis by administering an antagonist of AR". Pages 22 and 23 of the specification discloses a myriad of diverse molecules, which do not share *a substantial structural feature essential to a common utility*. The antagonists of AR as claimed include an anti-AR antibody and nucleic acid including antisense, micro-RNA (miRNA), short-hairpin RNA (shRNA) and short interfering RNA (siRNA).

These antagonists differ in structure, function and modes of action and have non-coextensive searches to such an extent that they are considered separately patentable. Therefore, the restriction has been set forth for each as separate Groups, irrespective of the format of the claims. If additional structurally distinct "antagonists" e.g. small molecules, are introduced during the course of prosecution that do not share *a substantial structural feature essential to a common utility* with the instantly recited "antagonists", then a supplemental restriction requirement may be issued.

3. The following is noted: Claim 43 include a recitation of a "method of diagnosing psoriasis or cancer in a mammal". This method encompass an anti-AR antibody as claimed. These methods differ in etiologies and therapeutic endpoints and have non-coextensive searches of such an extent that they are considered separately patentable. Therefore, the restriction has been set forth for each as separate Groups, irrespective of the format of the claims.

### Restrictions

4. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1-26, 28, 32 drawn to an antibody that competitively inhibits binding, pharmaceutical composition, hybridoma and polypeptide, classified in Class 424, subclass 130.1; Class 435, subclasses 335, and Class 530, subclass 350.

II. Claim 27, 29-31 drawn to an isolated polynucleotide, host cell and vector, classified in Class 536, subclass 23.1; Class 435, subclasses 325 and 320.1.

III. Claims 33-36, drawn to a method of inhibiting cancer cell growth, with an antagonist as it reads on an anti-AR antibody, classified in Class 424, subclass 178.1.

IV. Claims 33-34, drawn to a method of inhibiting cancer cell growth, with an antagonist as it reads on a nucleic acid, classified in Class 514, subclass 44.

V. Claims 37-41, drawn to a method of treating psoriasis, with an antagonist as it reads on an anti-AR antibody, classified in Class 424, subclass 130.1.

VI. Claims 37, 42, drawn to a method of treating psoriasis, with an antagonist as it reads on a nucleic acid, classified in Class 514, subclass 44.

VII. Claim 43, drawn to a method of diagnosing cancer, as it reads on an anti-AR antibody, classified in Class 435, subclass 4.

VIII. Claim 43-45, drawn to a method of detection psoriasis, as it reads on an anti-AR antibody, classified in Class 435, subclass 7.1.

5. Groups I and II are different products. Nucleic acids, vector, host cells, hybridomas, polypeptides and antibodies differ with respect to their structures, physicochemical properties and modes of action, which require non-coextensive searches. Therefore, they are patentably distinct.

Claim 27 recite known host cells. Therefore claim 27 is set forth with Group II as a host cell comprising nucleic acid sequences, which are recombinantly made and differ from hybridoma cells in structure and modes of production.

6. Groups III - VIII are different methods. These inventions are different with respect to ingredients, method steps, and endpoints, which require non-coextensive searches. Therefore, each method is patentably distinct.

7. (Groups I and III, V, VII, VIII) and (Groups II and IV/VI) are related as product and process of using. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)).

In the instant case the antibody of Group I can be used for affinity purification, in addition to the methods of treating and diagnosing recited.

In the instant case the polynucleotide of Groups II can be used as a probe to identify specific sequences and produce antibodies, in addition to the methods of treating recited.

8. (Groups I and VI) and (Groups II and III, V, VII and VIII) are not related as product and process of using.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, restriction for examination purposes as indicated is proper.

**Species Election**

10. Applicant is required to elect a particular anti-AR antibody and to provide the following information with respect to the elected species of anti-AR antibody (e.g. PAR34, PAR80, HuPAR34).

This application contains claims directed to the following patentably distinct species of the claimed *Groups I, III, V, VII, VIII* wherein:

Applicant is further required to elect a particular anti-AR antibody and to provide the following information with respect to the elected species:

> a particular light chain encoding variable region, (e.g. SEQ ID NO: 3, SEQ ID NO: 5, SEQ ID NO: 14);
> **and**
> a particular heavy chain encoding variable region, (e.g. SEQ ID NO: 2, SEQ ID NO: 4, SEQ ID NO: 12);

These species of anti-AR antibodies are distinct because each antibody possesses a unique structure as determined both by its heavy **and** light chain sequences, and by the pairing of those sequences to produce the antigen-binding site.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

11. *If one of the Groups III, IV, VII is elected,* applicant is required to elect a particular cancer selected from:

a. epidermal cancer, or
b. pancreatic cancer.

These species are distinct because the diseases differ with respect to their etiologies, the patient populations involved, and their therapeutic endpoints; thus each specific method of diagnosis and treating each of the diseases represents patentably distinct subject matter.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

12. This application contains claims directed to the following patentably distinct species of the claimed *Groups IV, VI* wherein:

Applicant is required to elect a particular nucleic acid antagonist selected from the following:

a. antisense,
b. micro-RNA (miRNA),
c. short-hairpin RNA (shRNA), or
d. short interfering RNA (siRNA).

These species are distinct because these nucleic acid antagonists differ in structure, function and modes of action; thus each condition represents patentably distinct subject matter.

Applicant is invited to distinguish between **a.** - **d.**, to avoid a separation between potentially related species.

Applicant is further required under 35 USC 121 (1) to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable and (2) to list all claims readable thereon including those subsequently added.

13. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

14. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

15. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. *Process claims that depend from or otherwise include all the limitations of the patentable product* will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined.

See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. *Failure to do so may result in a loss of the right to rejoinder.*

16. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.Any inquiry concerning this communication or earlier communications from the examiner should be directed to Aniruddho Ray Chaudhuri whose telephone number is 571-272-0953. The examiner can normally be reached on Monday thru Friday 8:30 - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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November 4, 2004

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